III. REMARKS

A. Status of the Claims

Claims 1-13 were originally filed with the case on June 26, 2003. Claims 1, 5, 9 and 13 were amended and claims 14-18 were added in a Preliminary Amendment filed on October 16, 2003. Claims 1, 4, 5, 8, 9, 11, 14, and 16 are amended herein and claims 3, 7, 11, and 15 are canceled herein. No claims are added herein. Support for the amendments can be found in the specification and in the claims as originally filed.

B. The Claims are Patentable over Penn and Yaacobi

The Action rejects all pending claims under § 103(a) as being unpatentable over Penn *et al.* and Yaacobi. The Action asserts that Penn teaches the use of anecortave acetate in a pharmaceutical formulation for the inhibition of angiogenesis of ocular conditions such as macular degeneration. The Action acknowledges that Penn lacks a teaching of the prevention of loss of vision associated with AMD, maintaining visual acuity associated with AMD, the inhibition of lesion growth and the inhibition of blood vessel growth associated with AMD (*i.e.*, the uses claimed in the pending claims). Nevertheless, the Action states that it would have been obvious to use the claimed compound for the claimed uses in light of Penn's teaching of the treatment of macular degeneration. Yaacobi is said to teach the use of a device, which can be implanted into the eye for drug delivery purposes and to mention the use of anecortave acetate in the device. Applicants respectfully traverse.

Penn describes a study investigating the capacity of anecortave acetate to inhibit retinal neovascularization using the rat model of retinopathy of prematurity. Penn does not discuss the administration of anecortave acetate to a patient. Furthermore, the rats used in the

study described in Penn were given 5 µl of a 10% suspension of anecortave acetate, which is equivalent to about 0.5 mg of anecortave acetate. The presently claimed invention is directed to the use of from 3 mg to 30 mg of anecortave acetate to treat human patients to inhibit the loss of visual acuity, maintain visual acuity, inhibit lesion growth, and inhibit blood vessel growth associated with age-related macular degeneration. The skilled artisan is well aware that, although animal models for testing compounds for treatment of human disease states are useful to predict the effectiveness of a compound against a particular disease, the dosage amounts to be administered to humans are not necessarily easily extrapolated from the amounts given to animals.

Yaacobi is directed to biocompatible implants for localized delivery of pharmaceutically active agents to the posterior segment of the eye. Yaacobi provides examples of the use of anecortave acetate in the implant. The example provided in Yaacobi describes the implantation of the described implant containing either 0.8 µM or 0.7 µM tablets of anecortave acetate onto the sclera of rabbits. The example illustrated that the implant containing the tablet implanted on the sclera delivered a generally constant amount of anecortave acetate to the rabbit retina and the choroids at the target site in the tested rabbit eyes. However, no dosage amounts applicable to human subjects are provided or suggested within Yaacobi.

For the foregoing reasons, Applicants respectfully request that the obviousness rejection based on Penn and Yaacobi be withdrawn.

C. Claims 1-4 Are Enabled

The Action next rejects claims 1-4 as lacking enablement under § 112, first paragraph. The Action states that the specification is enabling for inhibition of loss of visual acuity or

maintaining visual acuity but does not enable the prevention of loss of visual acuity. While Applicants disagree that the specification does not enable the prevention of loss of visual acuity, the claims have been amended herein to more clearly define the claimed subject matter. Claim 1, as amended, is directed to the inhibition of loss of visual acuity.

For the foregoing reasons, Applicants respectfully request that the enablement rejection of claims 1-4 be withdrawn.

D. Conclusion

Applicants respectfully request that the claims be considered as amended herein.

The Examiner is invited to contact the undersigned attorney at (817) 551-4321 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,

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